

**Michael Plishka | President**

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**Professional Experience Summary**

Founder and President of ZenStorming, a Design and Innovation Consultancy.  
Twenty+ years designing, developing and launching medical products

***FOCUS ON THE CUSTOMER***

*Clinical Relationship Builder*

*Extensive experience in Sterile Environments*

*Trained clinicians and sales staff on device use in cadaver and mock labs*

*Established hospital based training programs for engineers*

*Market Research studies*

*Product Research = Product Requirements = New Product Directions*

*Product Complaint Support*

*Assembled Clinical Advisory Boards to guide product portfolio strategy*

*Instructional Videos and Label Copy*

***APPLIED CREATIVITY***

*Idea Generation*

*Innovator for Next Generation Products*

*Product Platform Development*

*Strategic Technology Planning*

*Technology Assessment*

*Intellectual Property Portfolio Development*

*Expedited Project Feasibility*

*3D Printing and Prototyping*

*Product Problem Solving*

***REGULATORY SPECIALISMS***

*Presenter at 2008 International Silicone Conference,*

*“Working with Medical Device Companies – The Essentials”*

*QSR Procedures (Design Controls, GMP, GLP, etc.)*

*Validation and testing protocols for new products and processes*

*Risk Assessment Process development*

*Authorship of 510 (k) submissions*

*Engineering Regulatory Compliance*

Neuro Corn

## PROFESSIONAL EXPERIENCE

### *ZenStorming Solutions, LLC*

*4/08 to Present*

- Carefusion/BD – New Product Conception/Strategy/Design/Development, Development of Disruptive Innovation Portfolio, Technology Assessment, IP Development, Sales/Clinical Training, Mobile App Story-Boarding, Expert Witness Support
- Hollister – New Product Idea Generation - Brainstorming Moderation
- King Systems (Ambu) – Respiratory Products and Emergency Airway Access, New Product Design/Development
- Surgimatix – Endoscopic Suture Device Development, and Quality System Development
- Hines VA – Electrode Deployment Device Development, Grant Funding and Engineering Support
- AOK Inc. – New Product Development: Thoracic Access, Toy Robot Development
- Ferring Pharmaceuticals – Developed Marketing Awareness Campaign
- Testicular Cancer Society - Developed Marketing Awareness Campaign
- Baxter Healthcare – IP Portfolio Development
- EndoEvolution – Expert Witness (Ethicon EndoSurgery vs. EndoEvolution) Arbitration and Patent Case
- Hologic - Expert Witness (Ethicon EndoSurgery v. Hologic Inc and Suros Surgical Systems, Case No. 1:07-CV-00834)

### *Baxter Healthcare*

*6/06 to 4/08*

#### *Position: Engineering Specialist; Access Systems Business Unit*

- Lead Innovator for generating IP for Next Generation Vascular Access Products resulting in multiple cross platform patent applications in heavily populated patent landscape
- Spearheaded development of resources that enabled manufacture of prototypes in half the time at a cost savings of 50%.
- Determined the feasibility of new IV Access product and benchmarked against key competitive products in six months
- Engineering Lead for Market Research Studies
- Developed relationships with clinicians which resulted in six new hospital sites for engineers to study clinician behaviors.
- Led Clinical Advisory Board Meetings in conjunction with Marketing.
- Drafted business unit plan for World Wide Technology/Product Planning Committees
- Mentor for younger engineers
- Company Representative in off-site college recruitment program.
- Direct Supervisory Responsibility for Junior Engineer

### *Cardinal Health (Allegiance Healthcare Corporation)*

*4/99 to 6/06*

#### *Position: Engineering Specialist; Special Procedures Business Unit*

- Engineering Project Lead driving products from conception through launch while meeting aggressive timelines
- Physician Advisory Board Team Leader for new product development projects
- Technical Expert assessed and recommended new technologies and/or products for business development
- Developed patented, product platforms and line extensions that provided for 35% of all revenues in the Special Procedures business unit.
- Developed training materials and trained Sales Staff and Clinicians on new products in cadaver labs and lecture settings
- Developed and updated Quality System/Design Controls, minimizing documentation volume and time without sacrificing safety (Design Controls, Risk Analysis, GMP, GLP, etc.)
- Authored and performed validation and testing protocols for new products and processes
- Supported 510 (k) regulatory submissions
- Developed company-wide Technical Development Career track for non-degreed Designers/Technicians
- Direct supervisory responsibility for Designer and EDP (Engineering Development Program) Engineer
- Mentor for younger engineers
- Indirect managerial responsibility for cross-cultural Project Team
- Company Representative in off-site college recruitment program.

**Manan Medical Products**

3/95 to 4/99

**Position: New Product Development Engineer**

- Worked with clinicians to develop novel and patented catheter products
- Managed manufacturing scale-up through product launch.
- Developed advertising, labeling (instructions), packaging plans and manufacturing procedures for new products.
- Filed and successfully received 510(k) approval on new and modified products.
- Wrote and performed validation and testing protocols for products and processes.
- Head of Engineering Regulatory Compliance Team achieving ISO registration and passing FDA audit with no corrective action taken
- Developed Design Control and Hazard Analysis procedures as per QSR and ISO

**Hines VA Hospital/Loyola Medical Center**

3/91 to 5/94

**Position: Biomedical Engineer**

- Developed bi-polar surface electrode for use on perineum.
- Co-developed implantable "mesh" electrode for use on bladder wall.
- Co-designed supra-pubic indwelling catheter for use in bladder studies.
- Generated computer simulation of bladder in cooperation with University of Illinois.
- Co-authored papers which applied research to practical, diagnostic use.

**INVENTIONS (Partial List)**

US5730724 Drainage Catheter Apparatus  
US5989241 Drainage Catheter Apparatus  
US 7018343 Biopsy Needle and Device Containing the Same  
D478987S Biopsy device  
CA2413665 Multi-Use Surgical Cement Dispenser Apparatus And Kit For Same  
CA2429357 Improved Paracentesis Device Having Multiple Detachable Components  
WO03086201 Improved Biopsy Needle And Biopsy Device Containing The Same  
WO03000121 Multi-Use Surgical Cement Dispenser Apparatus And Kit For Same  
WO03022337 Improved Paracentesis Device Having Multiple Detachable Components  
Curable Material Injection Device-Pending  
Curable Material Mixing and Delivery Device -Pending  
Paracentesis Device - Pending  
Luer Activated Device –Three Patents Pending  
Biopsy Devices – Two Pending

**EDUCATION**

**Bachelor of Science Mechanical Engineering**

University of Illinois at Chicago

Honors: Phi Eta Sigma for Honor Roll in multiple consecutive semesters

**Master of Arts**

Loyola University of Chicago

**PUBLICATIONS**

“Mind Opening Exercise” Illustration in "Lifespan Human Development" (Sigelman, Rider, De George-Walker, 2013)

Walter, J. S., Wheeler, J. S., Zaszczurynski, P., & Plishka, M. "Urodynamic measure of urethral cross-sectional area: Application for obstructive uropathy." *Neurourology and urodynamics* 13.5 (1994): 571-582.

Damaser, M. S., Walter, J. S., & Plishka, M. "Letter." *International Urogynecology Journal* 5.3 (1994): 191-191.

Walter, J. S., Wheeler, J. S., Morgan, C., Zaszczurynski, P., & Plishka, M. "Measurement of urethral compliance in females with stress incontinence." *Engineering in Medicine and Biology Society, 1992 14th Annual International Conference of the IEEE*. Vol. 4. IEEE, 1992.

Walter, J. S., Wheeler, J. S., Morgan, C., Zaszczurynski, P., & Plishka, M. "Measurement of total urethral compliance in females with stress incontinence." *Neurourology and urodynamics* 12.3 (1993): 273-276.

Walter, J. S., Wheeler, J. S., Cogan, S. F., Plishka, M., Riedy, L. W., & Wurster, R. D. "Evaluation of direct bladder stimulation with stainless steel woven eye electrodes." *The Journal of urology* 150.6 (1993): 1990-1996.

## HONORS/SKILLS

### *Presentations:*

- Presenter at 2008 International Silicone Conference, "Working with Medical Device Companies – The Essentials"

### *Awards:*

- Received Foster G. McGaw Contribution for Ava-Tex™ Bone Cement Delivery System (2005).
- Received Karl D. Bays New Product Award for development of Temno Evolution Biopsy Device (2004).
- Received Karl D. Bays New Product Award for development of Safe-T-Centesis Drainage System (2003).
- Received Allegiance Innovation Award for development and launch of Ava-Tex™ Bone Cement Delivery System in nine months (2001).
- Received Technical Excellence Award from Technical Council in 2001 and 2003.

## ITEMIZED PROJECT EXPERIENCE ADDENDUM

**Innovation:** Worked with clinicians to design the following:

- Biliary Catheters
- General Drainage Catheters
- Nephrostomy Catheters
- Guide Wire Introducers
- MRI Compatible Biopsy Needles
- Vertebroplasty Systems
  - Delivery System
  - Mixing System
  - Access System
- Repositionable Para/thoracentesis Catheters
- Drainage Systems
- Fully Automatic Breast Biopsy Device
- Catheter Fixation Disk
- Interventional Drainage Bag
- Laryngoscope
- Anesthesia Filters
- Endoscopic Suture Device
- Tissue/Fiduciary Markers
- Surgical Heating Systems
- Introducer Sheaths

*Electrodes*

- Perineal
- Implantable Woven Mesh

*Vascular Access*

- Luer Activated Devices

**Clinical Procedural Attendance:**

- Biopsy
- Vertebroplasty
- PICC Placement
- Kyphoplasty
- Angioplasty/Stent Placement
- Interventional Drainage Catheter Placement
- Interventional Diagnostics
- Vascular Access

**Materials Knowledge:** Partial list of materials used in product developed:

- Implant grade steels
- MRI Compatible Materials
- Polycarbonate
- Polyurethane
- PMMA
- ABS
- Polypropylene
- Silicones
- PEEK
- Nylon

**Innovation Process:**

- Improved Brainstorming Processes
- Technical Expert involved in cross-business innovation
- Independent Reviewer of Cross-business products
- IP Generation and Portfolio Management
- Key Opinion/Clinical User Boards

**Process Engineering:** Manufacturing of the following devices:

- Interventional Drainage Catheters
- Needles
- Hand Held Injectors
- Cement Delivery Tubes
- Hot and Cold Pads
- Drainage Bags
- Guide Wire Catheters
- Luer Activated Devices
- Tissue Markers

**Anatomy/Physiology:** Working knowledge in the following areas:

- Human physiology
- Spine Mechanics
- Interventional Visualization Systems
- Vascular Biology
- Modelling of Heat Transfer under Anesthesia

**Coating/Impregnated Materials:** Experience with the following coatings:

- Hydrophilic Coating
- Antimicrobial Silver Coatings
- Parylene & PTFE Coating
- Lubricious materials (Impregnated)
- Antimicrobials (Impregnated)